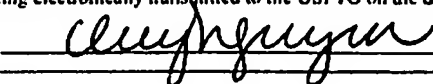


I hereby certify that this correspondence is being electronically transmitted to the USPTO on the date shown below.

Date: December 30, 2008

Signature: \_\_\_\_\_

 (Quyen B. Nguyen)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application No.: 10/686,891  
Confirmation No.: 7544  
Filing Date: October 15, 2003  
Inventor(s): Amir J. TEHRANI  
Title: BREATHING DISORDER DETECTION AND THERAPY  
DELIVERY DEVICE AND METHOD  
Examiner: Alyssa M. Alter  
Group Art Unit: 3762

---

**PETITION TO WITHDRAW HOLDING OF ABANDONMENT**

Mail Stop Issue Fee  
Commissioner for Patent  
P.O. Box 1450  
Alexandria, VA 22313-1450

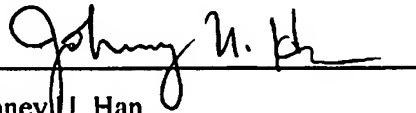
Sir:

This is in response to the Notice of Abandonment dated December 24, 2008. Applicants respectfully request withdrawal of the abandonment. A response to the Final Office Action dated June 17, 2008 was timely filed on December 17, 2008. Applicant filed a Request for Continued Examination (RCE) along with the appropriate extension request via EFS-Web. A copy of the filing is available on PAIR, but is also enclosed herewith:

1. Electronic Acknowledgement Receipt dated December 17, 2008
2. Request for Continued Examination (RCE) Transmittal for EFS-Web
3. Response to Final Office Action
4. Supplemental Information Disclosure Statement with PTO/SB08 form and one non-patent literature reference
5. Petition for Extension of Time
6. Fee Transmittal with appropriate payment of all fees

Applicants do not believe a fee is required. In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to Deposit Account No. 50-3973 referencing Attorney Docket No. RMXLNZ00100. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,



Johny U. Han  
Registration No. 45,565

**Customer No. 40518**  
Levine Bagade Han LLP  
2483 East Bayshore Road, Suite 100  
Palo Alto, CA 94303  
Direct: (650) 242-4217  
Fax: (650) 284-2180

## Electronic Acknowledgement Receipt

<b>EFS ID:</b>	4478358
<b>Application Number:</b>	10686891
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	7544
<b>Title of Invention:</b>	Breathing disorder detection and therapy delivery device and method
<b>First Named Inventor/Applicant Name:</b>	Amir J. Tehrani
<b>Customer Number:</b>	40518
<b>Filer:</b>	Johney U. Han/Quyen Nguyen
<b>Filer Authorized By:</b>	Johney U. Han
<b>Attorney Docket Number:</b>	RMXLNZ00100
<b>Receipt Date:</b>	17-DEC-2008
<b>Filing Date:</b>	15-OCT-2003
<b>Time Stamp:</b>	19:56:58
<b>Application Type:</b>	Utility under 35 USC 111(a)

### Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$960
RAM confirmation Number	4997
Deposit Account	
Authorized User	

### File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (If appl.)
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1	. Request for Continued Examination (RCE)	RMXLNZ00100_20081217_RCE_efs.pdf	639470 430e1fdd4a749d0e432794e6ba33ecc58e3ee2f8	no	3
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Information:					
2		RMXLNZ00100_20081217_response_final_oa_with_exhibits.pdf	357133 6b9906f5e03233c54f7981e6164c929856165ec4	yes	11
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Amendment Submitted/Entered with Filing of CPA/RCE		1	1	
	Claims		2	5	
	Applicant Arguments/Remarks Made in an Amendment		6	9	
	Miscellaneous Incoming Letter		10	11	
Warnings:					
Information:					
3		RMXLNZ00100_20081217_SIDS.pdf	108783 d990abd8f0e864c97248862a801fca0cc0bbe80	yes	3
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Information Disclosure Statement Letter		1	2	
	Information Disclosure Statement (IDS) Filed (SB/08)		3	3	
Warnings:					
Information:					
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Information:					
5	Extension of Time	RMXLNZ00100_20081217_extension_of_time.pdf	56478 4d2e2d52530abc5a6162175adf17dfa6364af07c	no	1
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Information:					

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<b>Warnings:</b>					
<b>Information:</b>					
<b>Total Files Size (in bytes):</b>				1385434	
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><b><u>New Applications Under 35 U.S.C. 111</u></b>          If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><b><u>National Stage of an International Application under 35 U.S.C. 371</u></b>          If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><b><u>New International Application Filed with the USPTO as a Receiving Office</u></b>          If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>					

# **REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL** (Submitted Only via EFS-Web)

Application Number	10686891	Filing Date	2003-10-15	Docket Number (if applicable)	RMXLN200100	Art Unit	3762
First Named Inventor	Amir J. TEHRANI			Examiner Name	Alyssa M. Alter		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application. Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

## **SUBMISSION REQUIRED UNDER 37 CFR 1.114**

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on \_\_\_\_\_

☐ Other \_\_\_\_\_

☒ Enclosed

☒ Amendment/Reply

☒ Information Disclosure Statement (IDS)

☐ Affidavit(s)/ Declaration(s)

☒ Other  
Petition for Extension of Time \_\_\_\_\_

## **MISCELLANEOUS**

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months \_\_\_\_\_  
(Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other \_\_\_\_\_

## **FEES**

☒ The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.  
The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to  
Deposit Account No 503973

## **SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED**

☒ Patent Practitioner Signature

☐ Applicant Signature

Doc code: RCEX

PTO/SB/30EFS (11-08)

Doc description: Request for Continued Examination (RCE)

Approved for use through 12/31/2008. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Signature of Registered U.S. Patent Practitioner			
Signature	/Johney U. Han/	Date (YYYY-MM-DD)	2008-12-17
Name	Johney U. Han	Registration Number	45565

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

*If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.*

## Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

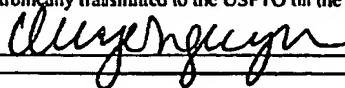
1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.



I hereby certify that this correspondence is being electronically transmitted to the USPTO on the date shown below.

Date: December 17, 2008

Signature: \_\_\_\_\_



(Quyen B. Nguyen)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application No.: 10/686,891  
Confirmation No.: 7544  
Filing Date: October 15, 2003  
Inventor(s): Amir J. TEHRANI et al.  
Title: BREATHING DISORDER DETECTION AND THERAPY  
DELIVERY DEVICE AND METHOD  
Examiner: Alyssa M. Alter  
Group Art Unit: 3762

---

**RESPONSE TO FINAL OFFICE ACTION**

Mail Stop RCE  
Commissioner for Patent  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This is in response to the final Office Action dated June 17, 2008 for which a response was due on September 17, 2008. Filed herewith is a Petition and fee for a three-month extension of time, thereby extending the deadline for response to December 17, 2008. Accordingly, this response is timely filed. Reconsideration and allowance of the pending claims, as amended, in light of the Remarks presented herein are respectfully requested. A Request for Continued Examination is also being submitted.

**Amendments to the Claims** are reflected in the listing of claims which begins on page 2 of this paper.

**Remarks** begin on page 6 of this paper.

## AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

**In the claims**

1. - 122. (Cancelled).

123. (Currently Amended): A device for managing respiration of a patient comprising:

at least one electrode configured to ~~be coupled to~~ target a diaphragm or phrenic nerve tissue of a patient's body wherein the at least one electrode is configured to deliver electrical stimulation to the diaphragm or phrenic nerve tissue to thereby elicit a diaphragm response; and

a stimulator configured to deliver a stimulation signal to the diaphragm or phrenic nerve tissue through the at least one electrode in response to sensed respiration due to phrenic nerve activity detected internally within the patient's body to elicit an inspiration duration different from an intrinsic inspiration duration of an intrinsic breath.

124. (Previously Presented): The device of claim 123 wherein the stimulator is configured to deliver a stimulation signal to the tissue through the at least one electrode to elicit an increased inspiration duration with respect to an intrinsic inspiration duration of an intrinsic breath.

125. (Previously Presented): The device of claim 123 wherein the stimulator is configured to deliver a stimulation signal to the tissue through the at least one electrode to elicit a decreased exhalation duration with respect to an intrinsic exhalation duration of an intrinsic breath.

126. (Currently Amended): A device for managing respiration of a patient comprising:

at least one electrode configured to ~~be coupled to~~ target a diaphragm or phrenic nerve tissue of a patient's body wherein the at least one electrode is configured to deliver electrical stimulation to the diaphragm or phrenic nerve tissue to thereby elicit a diaphragm response; and

a stimulator configured to deliver a stimulation signal to the diaphragm or phrenic nerve tissue through the at least one electrode in response to sensed respiration due to phrenic nerve activity detected internally within the patient's body to elicit an exhalation duration different from an intrinsic exhalation duration of an intrinsic breath.

127. (Currently Amended): The device of claim ~~[[128]]~~ 123 wherein the stimulator is configured to deliver a stimulation signal to the tissue through the at least one electrode to elicit a decreased exhalation duration with respect to an intrinsic exhalation duration of an intrinsic breath.

128. – 140. (Cancelled).

141. (Previously Presented): The device of claim 123 further configured to elicit an inspiration rate different from an intrinsic inspiration rate.

142. (Previously Presented): The device of claim 123 further configured to elicit an exhalation rate different from an intrinsic exhalation rate.

143. – 148. (Cancelled).

149. (Previously Presented): The device of claim 124 wherein the stimulator is configured to deliver a stimulation signal to the tissue through the at least one electrode to elicit a slow elongated inspiration.

150. (Previously Presented): The device of claim 123 wherein the stimulator is configured to deliver a stimulation signal to the tissue through the at least one electrode to elicit a fast, short inspiration.

151. (Previously Presented): The device of claim 123 wherein the stimulator is configured to deliver low level sequential stimulations.

152. (Previously Presented): The device of claim 125 wherein the stimulator is configured to deliver a stimulation signal that is directed to manipulating blood gases to thereby treat apnea.

153. (Currently Amended): A device for managing respiration of a patient comprising:

at least one electrode configured to ~~be coupled to~~ target a diaphragm or phrenic nerve tissue of a patient's body wherein the at least one electrode is configured to deliver electrical stimulation to the diaphragm or phrenic nerve tissue to thereby activate at least a portion of ~~the~~ the diaphragm; and

a stimulator configured to deliver a stimulation signal to the diaphragm or phrenic nerve tissue through the at least one electrode in response to sensed respiration due to phrenic nerve activity detected internally within the patient's body to elicit an inspiration duration different from an intrinsic inspiration duration of an intrinsic breath.

154. (Previously Presented): The device of claim 153 wherein the stimulator is configured to deliver a stimulation signal to the tissue through the at least one electrode to elicit an increased inspiration duration with respect to an intrinsic inspiration duration of an intrinsic breath.

155. (Previously Presented): The device of claim 153 wherein the stimulator is configured to deliver a stimulation signal to the tissue through the at least one electrode to elicit a decreased exhalation duration with respect to an intrinsic exhalation duration of an intrinsic breath.

156. (Previously Presented): The device of claim 153 wherein the stimulator is configured to deliver a stimulation signal to the tissue through the at least one electrode to

elicit a decreased exhalation duration with respect to an intrinsic exhalation duration of an intrinsic breath.

157. (Previously Presented): The device of claim 153 further configured to elicit an inspiration rate different from an intrinsic inspiration rate.

158. (Previously Presented): The device of claim 153 further configured to elicit an exhalation rate different from an intrinsic exhalation rate.

**REMARKS**

Claims 123-127, 141, 142 and 149-158 were pending in the present application. By virtue of this response, claims 123, 126, 127, and 153 have been amended. Accordingly, claims 123-127, 141, 142 and 149-158 are currently under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. No new matter has been added.

**Rejections under 35 U.S.C. § 102(b)**

Claims 123-127, 141-124 and 149-158 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Testerman et al. (US 5,522,862).

In response, independent claim 123 has been amended to recite “at least one electrode configured to target a diaphragm or phrenic nerve tissue of a patient's body wherein the at least one electrode is configured to deliver electrical stimulation to the diaphragm or phrenic nerve tissue to thereby elicit a diaphragm response”. (Specification, [0038].) Independent claims 126 and 153 have been similarly amended to recite the at least one electrode being configured to target the diaphragm or phrenic nerve tissue (which is in direct communication with the diaphragm) to elicit a diaphragm response.

On the other hand, Testerman et al. shows and describes “stimulation of the musculature of the upper airway in synchrony with the inspiratory phase of the respiratory cycle” and fails to show or describe direct stimulation of the diaphragm or phrenic nerve tissue. (Testerman et al., 5: 13-15.) Rather, “the muscle stimulated is the genioglossus muscle stimulated by a cuff electrode placed around the hypoglossal nerve.” (Testerman et al., 5: 60-62 & Figs. 33-34.)

Electrically stimulating the diaphragm or phrenic nerve tissue to mitigate an obstructive disorder is an entirely different process from electrically stimulating a hypoglossal nerve. The hypoglossal nerve is a cranial nerve and emerges from or enters the skull to primarily supply the muscles of the tongue. (See attached Exhibit A, <http://www.medterms.com/script/main/art.asp?articlekey=7652>.) On the other hand, the diaphragm muscle controls respiration and is itself controlled by the phrenic nerve. (See attached Exhibit B, <http://www.medterms.com/script/main/art.asp?articlekey=2983>.) Thus,

as taught by Testerman et al., the application of electrical stimulation to the hypoglossal nerve affects only the genioglossus muscle to open the airway to the lungs yet does not affect the diaphragm itself to mitigate any obstructive airway disorder, as presently claimed.

However, the application of electrical stimulation to the diaphragm itself or to the phrenic nerve, which in turn controls the diaphragm, does directly affect respiration as the diaphragm itself controls respiration. Thus, applying electrical stimulation to the diaphragm or phrenic nerve cannot be considered equivalent to stimulating the hypoglossal nerve which merely contracts the genioglossus muscle yet does not affect the act of respiration itself.

Therefore, Testerman et al. cannot anticipate independent claims 123, 126, and 153. The dependent claims depend ultimately from claims 123, 126, and 153 and are patentable for at least the same reasons. Accordingly, Applicant respectfully requests the reconsideration and withdrawal of the rejections under 35 USC §102(b).

#### **Rejections under 35 U.S.C. § 102(e)**

Claims 123-127, 141-142 and 149-158 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Ignagni et al. (US Patent Publication 20050021102 A1)

In response, independent claim 123 has been amended to recite “a stimulator configured to deliver a stimulation signal to the diaphragm or phrenic nerve tissue through the at least one electrode in response to sensed respiration due to phrenic nerve activity detected internally within the patient’s body”. (Specification, [0012].) Independent claims 126 and 153 have been similarly amended to recite delivering a stimulation signal to the diaphragm or phrenic nerve tissue through the at least one electrode in response to phrenic nerve activity which is detected within the patient’s body via an internally implanted sensor.

On the other hand, Ignagni et al. shows and describes a device which is configured to deliver electrical stimulation on a continuous or periodic basis which is preset. (Ignagni et al., [0030].) Ignagni et al. only describes utilizing physiologic activity where an air flow sensor external to the body can be provided with an external mechanical ventilator for detecting the inspiratory or expiratory air flow. (Ignagni et al., [0035] & Fig. 4.) However, the sensing of air flow is an entirely different mode of sensing from phrenic nerve activity in mechanism and principle. Moreover, the air flow sensor is a sensor which is necessarily

positioned external to the patient's body and cannot be said to be internally within the patient's body, as presently claimed.

Therefore, Ignagni et al. cannot anticipate independent claims 123, 126, and 153. The dependent claims depend ultimately from claims 123, 126, and 153 and are patentable for at least the same reasons. Accordingly, Applicant respectfully requests the reconsideration and withdrawal of the rejections under 35 USC §102(e).

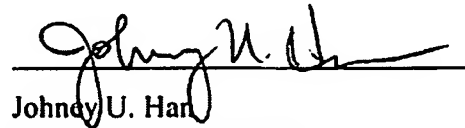


### CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to Deposit Account No. 50-3973 referencing Attorney Docket No. RMXLNZ00100. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,



Johnny U. Han  
Registration No. 45,565

Customer No. 40518  
Levine Bagade Han LLP  
2483 East Bayshore Road, Suite 100  
Palo Alto, CA 94303  
Direct: (650) 242-4217  
Fax: (650) 284-2180

## EXHIBIT A

10/16/2008

Hypoglossal nerve definition - Medici...

[close window](#)



Source: <http://www.medterms.com>

MedTerms is the Medical Dictionary of MedicineNet.com

### Definition of Hypoglossal nerve

**Hypoglossal nerve:** The hypoglossal nerve is the twelfth cranial nerve. The twelve cranial nerves, the hypoglossal nerve included, emerge from or enter the skull (the cranium), as opposed to the spinal nerves which emerge from the vertebral column.

The hypoglossal nerve supplies the muscles of the tongue. (The Greek "hypo-", under and "-glossal" from A"glossa", the tongue = under the tongue).

Paralysis of the hypoglossal nerve affects the tongue. It impairs speech (it sounds thick) and causes the tongue to deviate toward the paralyzed side. In time, the tongue diminishes in size (atrophy).

*Last Editorial Review: 12/1/1998 5:12:00 PM*

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## EXHIBIT B

10/16/2008

Diaphragm (muscle) definition - Medi...

[close window](#)



Source: <http://www.medterms.com>

MedTerms is the Medical Dictionary of MedicineNet.com

### Definition of Diaphragm (muscle)

**Diaphragm (muscle):** The muscle that separates the chest (thoracic) cavity from the abdomen. The diaphragm is the main muscle of respiration. Contraction of the diaphragm muscle expands the lungs during inspiration when one is breathing air in. We rely heavily on the diaphragm for our respiratory function so that when the diaphragm is impaired, it can compromise our breathing. The nerve that controls the diaphragm is the phrenic nerve, which originates much high (at C3-C5). During development the diaphragm moves down and drags the phrenic nerve with it.

*Last Editorial Review: 7/18/2004*

Common Misspellings: diaphram (muscle)

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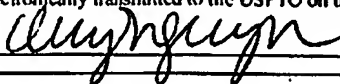
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Date: December 17, 2008

Signature: \_\_\_\_\_

 (Quyen B. Nguyen)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application No.: 10/686,891  
Confirmation No.: 7544  
Filing Date: October 15, 2003  
Inventor(s): Amir J. TEHRANI et al.  
Title: BREATHING DISORDER DETECTION AND THERAPY  
DELIVERY DEVICE AND METHOD  
Examiner: Alyssa M. Alter  
Group Art Unit: 3762

---

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Mail Stop RCE  
Commissioner for Patent  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §1.97 and §1.98, Applicants submit for consideration in the above-captioned application the documents listed on the attached Form PTO/SB/08a/b. Copies of the documents are also submitted herewith. The Examiner is requested to make these documents of record.

Applicant wishes to bring to the Examiner's attention, related applications and patents commonly assigned to the assignee of the present invention: U.S. Application No. 10/966,474 filed October 15, 2004.

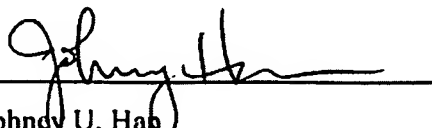
This Information Disclosure Statement is submitted before the mailing of a first Office Action after the filing of a Request for Continued Examination under § 1.114; accordingly, no fee or separate requirements are required. However, if applicable, a certification under 37 C.F.R. §1.97(e)(1) has been provided.

Applicants would appreciate the Examiner initialing and returning the Form PTO/SB/08a/b, indicating that the information has been considered and made of record herein.

The information contained in this Information Disclosure Statement under 37 C.F.R. §1.97 and §1.98 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to Deposit Account No. 50-3973 referencing Attorney Docket No. RMXLNZ00100. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,



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Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/686,891
				Filing Date	October 15, 2003
				First Named Inventor	Amir J. TEHRANI
				Art Unit	3762
				Examiner Name	Alyssa M. Alter
Sheet	1	of	1	Attorney Docket Number	RMXLNZ00100

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	5423372	06-13-1895	Kearney	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>

\*EXAMINER: Initial if information considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kind Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 801.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	2.	SHIER, D. et al, Hole's Human Anatomy & Physiology, pp. 798 (2 pages total).	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

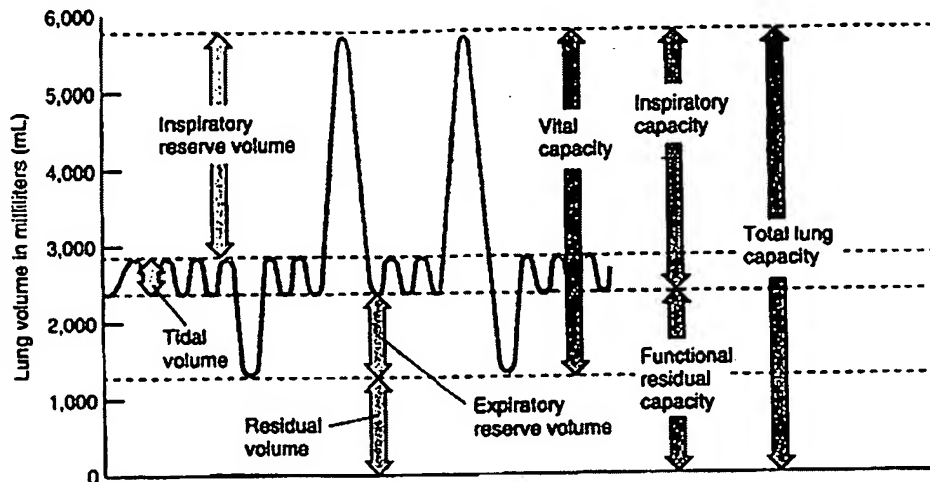
Examiner Signature	Date Considered
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**H**  
**HOLE'S**

**ANATOMY & PHYSIOLOGY**

**DAVID SHIER**  
**JACKIE BUTLER**  
**RICKI LEWIS**



**FIGURE 19.26**  
Respiratory volumes and capacities.

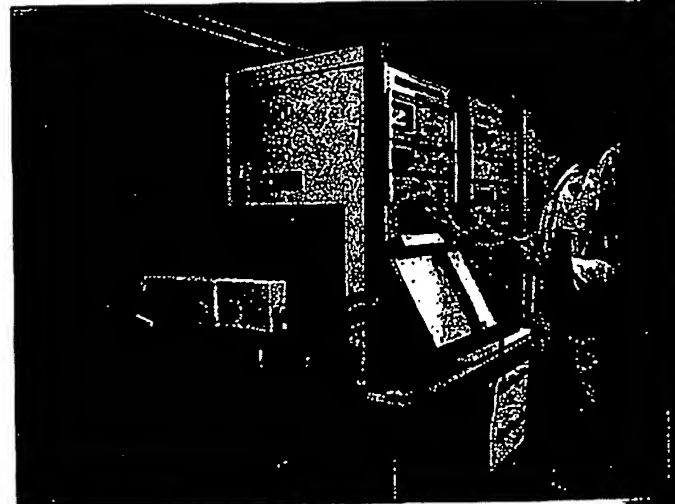
The tidal volume (500 mL) plus the inspiratory reserve volume (3,000 mL) gives the **inspiratory capacity** (3,500 mL), which is the maximum volume of air a person can inhale following a resting expiration. Similarly, the expiratory reserve volume (1,100 mL) plus the residual volume (1,200 mL) equals the **functional residual capacity** (2,300 mL), which is the volume of air that remains in the lungs following a resting expiration.

The vital capacity plus the residual volume equals the **total lung capacity** (about 5,800 mL). This total varies with age, sex, and body size.

Some of the air that enters the respiratory tract during breathing fails to reach the alveoli. This volume (about 150 mL) remains in the passageways of the trachea, bronchi, and bronchioles. Since gas exchanges do not occur through the walls of these passages, this air is said to occupy **anatomic dead space**.

Occasionally, air sacs in some regions of the lungs are nonfunctional due to poor blood flow in the adjacent capillaries. This creates **alveolar dead space**. The anatomic and alveolar dead space volumes combined equal **physiologic dead space**. In a normal lung, the anatomic and physiologic dead spaces are essentially the same (about 150 mL).

A spirometer (fig. 19.27) is used to measure respiratory air volumes (except the residual volume). These measurements are used to evaluate the course of respiratory illnesses, such as emphysema, pneumonia, lung cancer, and bronchial asthma. Table 19.4 summarizes the respiratory air volumes and capacities.



**FIGURE 19.27**  
A spirometer can be used to measure respiratory air volumes.

## Alveolar Ventilation

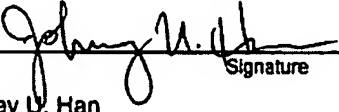
The amount of new atmospheric air that is moved into respiratory passages each minute is called the **minute ventilation**. It equals the tidal volume multiplied by the breathing rate. Thus, if the tidal volume is 500 mL and the breathing rate is 12 breaths per minute, the minute ventilation is  $500 \text{ mL} \times 12$ , or 6,000 mL per minute. However, much of the new air remains in the physiologic dead space.

The volume of new air that does reach the alveoli and is available for gas exchange is calculated by subtracting the physiologic dead space (150 mL) from the tidal volume (500 mL). The resulting volume (350 mL) multiplied by the breathing rate (12 breaths per minute) is the **alveolar ventilation rate** (4,200 mL per minute). The alveolar ventilation rate is a major factor affecting the concentrations of oxygen and carbon dioxide in the alveoli.

- 1 What is tidal volume?
- 2 Distinguish between inspiratory and expiratory reserve volumes.
- 3 How is vital capacity measured?
- 4 How is the total lung capacity calculated?



Under the paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

<b>PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)</b> <b>FY 2009</b> <i>(Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).)</i>		Docket Number (Optional) <b>RMXLNZ00100</b>	
Application Number <b>10/686,891</b>		Filed <b>October 15, 2003</b>	
For <b>BREATHING DISORDER DETECTION AND THERAPY DELIVERY DEVICE AND METHOD</b>			
Art Unit <b>3762</b>		Examiner <b>Alyssa M. Alter</b>	
This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application. The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):			
	<u>Fee</u>	<u>Small Entity Fee</u>	
<input type="checkbox"/> One month (37 CFR 1.17(a)(1))	\$130	\$65	\$ _____
<input type="checkbox"/> Two months (37 CFR 1.17(a)(2))	\$490	\$245	\$ _____
<input checked="" type="checkbox"/> Three months (37 CFR 1.17(a)(3))	\$1110	\$555	\$ <u>555</u>
<input type="checkbox"/> Four months (37 CFR 1.17(a)(4))	\$1730	\$865	\$ _____
<input type="checkbox"/> Five months (37 CFR 1.17(a)(5))	\$2350	\$1175	\$ _____
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. <input type="checkbox"/> A check in the amount of the fee is enclosed. <input checked="" type="checkbox"/> Payment by credit card. <del>Form PTO-2038 is attached.</del> <input type="checkbox"/> The Director has already been authorized to charge fees in this application to a Deposit Account. <input type="checkbox"/> The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number _____ <b>WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.</b>			
I am the <input type="checkbox"/> applicant/inventor. <input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed (Form PTO/SB/96). <input checked="" type="checkbox"/> attorney or agent of record. Registration Number <u>45,565</u> <input type="checkbox"/> attorney or agent under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____			
 _____ Johny U. Han Typed or printed name		_____ December 17, 2008 _____ Date (650) 242-4217 Telephone Number	
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.			
<input checked="" type="checkbox"/> Total of <u>1 of 1</u> forms are submitted.			

This collection of information is required by 37 CFR 1.136(a). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 6 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

## Electronic Patent Application Fee Transmittal

<b>Application Number:</b>	10686891			
<b>Filing Date:</b>	15-Oct-2003			
<b>Title of Invention:</b>	Breathing disorder detection and therapy delivery device and method			
<b>First Named Inventor/Applicant Name:</b>	Amir J. Tehrani			
<b>Filer:</b>	Johney U. Han/Quyen Nguyen			
<b>Attorney Docket Number:</b>	RMXLNZ00100			
Filed as Small Entity				
<b>Utility under 35 USC 111(a) Filing Fees</b>				
<b>Description</b>	<b>Fee Code</b>	<b>Quantity</b>	<b>Amount</b>	<b>Sub-Total in USD(\$)</b>
<b>Basic Filing:</b>				
<b>Pages:</b>				
<b>Claims:</b>				
<b>Miscellaneous-Filing:</b>				
<b>Petition:</b>				
<b>Patent-Appeals-and-Interference:</b>				
<b>Post-Allowance-and-Post-Issuance:</b>				
<b>Extension-of-Time:</b>				
Extension - 3 months with \$0 paid	2253	1	555	555

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
<b>Miscellaneous:</b>				
Request for continued examination	2801	1	405	405
<b>Total in USD (\$)</b>				<b>960</b>